Applicant: Theresa A. Hadlock et al.

Attorney's Docket No.: 00786-446002

Serial No. : 10/849,527 Filed : May 19, 2004 Page : 11 of 13

REMARKS

Claims 1-59 are in the case. Claims 1, 17, 34 and 43-46 have been amended. Claims 47-59 have been added by amendment. Claims 2-16, 18-33, 35-39 and 41-42 remain unchanged. No new matter has been added.

In the Office Action mailed January 20, 2004 in the parent application (U.S.S.N. 09/774,397) claims 1, 4, 6 and 7 were rejected as being unpatentable over Stensaas et al, and claims 2-3, 8-18, 40-43, 45-46 and 59 were rejected as being unpatentable over Butler et al. in view of Stensaas et al, Goosen, and Hadlock et al. ("A Polymer Foam Conduit Seed.."). Claims 19-39, 47-49 and 55-58 have been rejected as being unpatentable over these references further in view of Dionne.

These rejections are respectfully traversed.

In response to arguments submitted previously by Applicants, the Examiner stated in the January 20, 2004 Office Action that "it would have been obvious to form a conduit having any number of spiraled rotations, including at least $3^{1}/_{2}$ full rotations." Thus, it is the Examiner's position that it would have been obvious to modify the device described by Stensaas to have at least $3^{1}/_{2}$ full rotations. Applicants respectfully disagree.

It is *Applicants* who recognized that, to obtain successful regeneration, both the percent open area of the conduit and the total surface area of the conduit should be maximized. There is simply no recognition in Stensaas, or in any of the art of record, that would have led the artisan to have increased the number of rotations in the Stensaas device. On the contrary, the artisan would have expected the Stensaas device to function properly as constructed, and would have viewed modifying it to include additional rotations to be unnecessary and to increase the cost of the device without any expected benefit.

The Examiner proposes that the artisan would have been motivated to increase the rotations of the Stensaas device "so as to tightly secure nerve endings in an end-to-end fashion. It is inherent that more than one full rotation will securely hold the nerve ends in the desired fashion." Applicants respectfully disagree. The artisan would not have had this motivation

Applicant: Theresa A. Hadlock et al. Attorney's Docket No.: 00786-446002

Serial No.: 10/849,527 Filed: May 19, 2004 Page: 12 of 13

because, in fact, it is <u>undesirable</u> to wrap the nerve ends tightly, as this may result in nerve compression syndrome.

Thus, there is no motivation in the cited art that would have suggested to the artisan the modification of Stensaas proposed by the Examiner. The only motivation is found in *Applicants'* own specification. It is axiomatic that Applicants' specification cannot be used as a blueprint to modify the prior art.

Claims 2-3, 8-18, 43, and 45-46 are patentable for the same reason as claim 1, discussed above. None of the cited references teaches or fairly suggests a conduit including a support in the form of a roll, a cross-section of the roll approximating a spiral that includes at least 3¹/₂ full rotations. With the exception of Stensaas, none of the cited references teaches or suggest a rolled support in which a cross-section of the roll approximates a spiral of any kind. Butler discloses a pre-formed, cylindrical cell encapsulating device. Hadlock also teaches a pre-formed cylindrical structure, formed, e.g., by injection molding. Goosen and Dionne are directed to encapsulation of cells, and add nothing of relevance regarding spiral structures.

With regard to claims 40-42, 47, 58 and 59, none of the cited references discloses or suggests a method that includes rolling a support around a nerve. Instead, Butler discloses a preformed, cylindrical cell encapsulating device that is implanted into an individual to supply therapeutic substances to the individual. Stensaas discloses a pre-formed (e.g., molded) cylindrical prosthesis into which the ends of a severed nerve can be inserted. Hadlock also teaches a preformed foam conduit that is seeded with cells and implanted. Goosen and Dionne describe methods of encapsulating cells and implanting the encapsulated cells in a patient.

In view of the above, Applicants respectfully request that these rejections be withdrawn.

Applicant: Theresa A. Hadlock et al. Attorney's Docket No.: 00786-446002

Serial No.: 10/849,527 Filed: May 19, 2004 Page: 13 of 13

Enclosed is a \$525 check for excess claim fees. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 00786-446002.

Respectfully submitted,

16, No. 30, 175

Celia H. Leber

Reg. No. 33,524

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

20864683.doc